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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,947	10/02/2003	Stanton J. Rowe	PVI-S790	9719

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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	PAPER NUMBER
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

SR

Office Action Summary	Application No. 10/677,947	Applicant(s) ROWE, STANTON J.	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2006*.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38,43-46,52-62,67-72 and 74-89* is/are pending in the application.
4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-18,20-23,31,32,43,44,59,69-71 and 76-89* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on *13 October 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/18/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 19,24-30,33-38,45,46,52-58,60-62,67,68,72,74 and 75.

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian Pellegrino

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-13,16,18,20,21,23,31,32,43,44,59,69,70 are rejected under 35 U.S.C. 102(b) as being anticipated by Letac et al. (EP 850607). Fig. 4b shows a valve prosthesis **13** having a support stent **10** and a valve assembly **14** comprising a flexible conduit having an inlet and outlet end. It can also be seen the valve assembly comprises longitudinal support beams **17** attached to the valve material and thus attached to the stent. Additionally, it can be seen that the support frame present at the inlet end is wider in diameter at the inlet end than the flexible conduit since it placed around the outside of the flexible conduit. The device is configured that an artificial sinus is formed adjacent to the valve assembly, see Fig. 6c with the leaflet portions held entirely away from the stent **10** via cover **19**. Figs. 2a,2b show the stent having an annular frame. Letac et al. disclose the valve prosthesis can have a tricuspid configuration, col. 22, lines 11-20. Letac also discloses the valve is designed to have collapsible slack to block reverse flow and alters laminar flow, col. 5, lines 11-16, col. 12, lines 42-51. Letac additionally discloses biocompatible material is used for the valve, col. 4, lines 16,17. The material for the valve can be polyethylene terephthalate or pericardial tissue, col. 17, lines 18-48. The support beams can be construed to be "substantially equidistant and parallel". Letac discloses the support beams are chemically adhered to the stent and the valve can be stitched , col. 16, lines 3-5,36,37. The beams are fully capable of being made by injection molding or machining and the valve is fully capable of being forged or dipped. Letac discloses the stent can be expanded from about 4-26mm, col. 9, lines 41-43. Fig. 12a shows the frame having a deployable construction suitable for being deployed by means of deployment device, balloon.

Claims 76-81,83-86,88 are rejected under 35 U.S.C. 102(a) as being anticipated by Park et al. (EP 1264582). Fig. 1 shows a valve prosthesis with support stent structure having a first portion **6** with a first diameter **10** greater than second portion **16** having a second diameter **18**. It can also be seen there is a valve assembly **12**. It can be seen the device has a tricuspid configuration, **A1**,**A2**,**A3**. Please note the intended use carries no weight in the absence of any distinguishing structure.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 14,17,22,71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Letac et al. (EP 850607) in view of Zakai et al. (2003/153974). Letac et al. is explained supra. However, Letac fails to disclose the valve assembly body made of polyethylene terephthalate and leaflets made from polyurethane and to have bores in the beams for stitching or to roll the valve assembly over the support stent at the inlet or to reinforce the pliant valve material with PET. Zakai et al. teach the main body is made from polyethylene terephthalate and leaflets made from polyurethane, paragraph 45. Zakai et al. also teach the support beams include bores for stitching of the valve to the frame, paragraph 108. Zakai et al. teach (Fig. 2) the valve assembly is rolled over the support stent at the inlet to enhance sealing of the device, paragraph 112. Zakai et al. also teach the pliant material is reinforced with PET, paragraph 117. It would have been obvious to one of ordinary skill in the art to utilize the materials PET and polyurethane for the body and leaflets as taught by Zakai et al. in the valve prosthesis of Letac et al. such that it provides a more durable valve and biocompatible since these materials are inert. It would have been obvious to one of ordinary skill in the art to incorporate the bores in the beams as taught by Zakai et al. in the beams of the valve device of Letac et al. such that it prevents the beams from coming unattached from the valve structure in the patient. It would have also been obvious to roll over the valve assembly as taught by Zakai et al. with the valve prosthesis of Letac et al. such that it improves the seal of the valve and reduces the likelihood of any leakage. It would have also been obvious to one of ordinary skill in the art to reinforce the valve assembly with PET as taught by Zakai et al. in the prosthesis of Letac et al. such that the valve device is capable of withstanding strong blood pressure.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Letac et al. (EP 850607) in view of Bailey et al. (6458153). Letac et al. is explained supra. Letac also discloses the stent is made of metal, col. 6, line 29. However, Letac fails to disclose the stent is made of nickel titanium. Bailey et al. teach that nickel titanium is used for valve prosthesis stents (col. 5, lines 33-38) because of its superelastic properties. It would have been obvious to one of ordinary skill in the art to substitute materials and use nickel titanium for the stent as taught by Bailey et al. with the valve prosthesis of Letac et al. such that it possesses more flexibility.

Claims 82,87,89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (EP 1264582) in view of Zakai et al. (2003/153974). Park et al. is explained supra. However, Park et al. fail to disclose the valve assembly of pericardial tissue and the expandable frame of metal and to stitch the stent to the valve. Zakai et al. is also explained supra. Zakai et al. additionally discloses the valve is made of pericardial tissue and the stent is made of metal, paragraphs 99,100. It would have been obvious to one of ordinary skill in the art to incorporate stitching to secure the stent to the valve as taught by Zakai et al. with the valve device of Park et al. and utilize a metal frame also taught by Zakai such that it enhances visibility when implanting the device and to utilize a natural material with good compliance.

Response to Arguments

Applicant's arguments filed 10/13/06 have been fully considered but they are not persuasive. Applicant argues that the Letac fails to disclose the slack portions of the leaflets to be held entirely away from the stent. However, as mentioned above, see Fig. 6c of Letac. In response to applicant's argument that the Letac reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., integral or directly attached longitudinal support beams to the stent) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It can be construed that Letac has the support beams indirectly attached to the stent. In response to applicant's argument that the Park et al. prosthesis is for use in a gastrointestinal system and that the inlet end is not the end that the Applicant recites as "first portion", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The Applicant has not distinguished any difference in structure between the claims rejected over Park other than a difference in what is considered first and second portions. The use of "first and second" are just nominal recitations and any conduit can have its end arbitrarily called first and second ends as long as they meet the structure. In this instance Park's device has the structure of the claims rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-F (8:30am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian E Pellegrino